APR 2 0 2001

510(k) Summary
re: **K 003145**
OriGen Bladder Holder

October 6, 2000

Common Name: Bladder Holder, Classification 74DWC
Classification Name: controller, cardiopulmonary bypass (per 21CFR 870.4250)

The OriGen Bladder Holder is intended to support a silicone bladder and provide an alarm signal when the silicone bladder deflates, in procedures lasting less than six hours.. It is substantially equivalent to the Seabrook ECMO-TEMP™ Bladder Holder, model SMS-3200, approved under 510(k) submission K873699

The intended use and design of both devices are functionally equivalent. It should be noted however, that the predicate device includes an electronics box for controlling an attached pump, but the OriGen Bladder Holder does not include that portion of the predicate device. Instead, it has an internal, battery powered alarm, and a switch that may be used to signal an external alarm.

The function and construction of the systems is nearly identical. Both systems hold a silicone bladder and a captive plunger follows the bladder, engaged by light spring pressure. If the bladder deflates past a user-determined setpoint, an internal switch is tripped. In the predicate device, these switches triggered an external electronics box, but in the OriGen Bladder Holder, it triggers an internal battery-powered alarm. Through performance testing, OriGen has concluded that the Bladder Holder system is durable and at least as safe and effective as the predicate device. This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Sincerely,

Richard Martin
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

OriGen Biomedical, Inc.
c/o Mr. Richard Martin
President
2525 Hartford Road
Austin, TX 78703

Re: K003145
Trade Name: OriGen (silicon bladder) Holder
Regulatory Class: II(two)
Product Code: DWC
Dated: January 18, 2001
Received: January 23, 2001

Dear Mr. Martin:

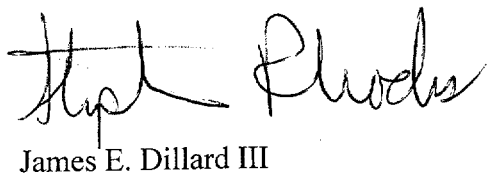
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510 (k) Number: K003145

Device name: OriGen (silicone bladder) Holder

Indications for Use:

The device is intended to support a disposable silicone reservoir, which is used as part of an extracorporeal circuit, and to provide an alarm signal when the reservoir deflates, in extracorporeal procedures lasting less than six hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over the Counter Use ___ (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003145